

REMARKS

Claims 1-3, 7-11,13, 15, 16, 18-25, 28, 29, 31, 32, 34-37, 39, 40 and 42 are currently pending in this application. Claims 1, 29 and 35 have been amended herein. Claims 8 and 42 have been canceled. Claims 4-6, 17, 28, 30, 33, 38 and 41 have been withdrawn as the result of a restriction requirement. Applicants reserve the right to pursue claims 4-6, 17, 28, 30, 33, 38 and 41 in a divisional application. No new matter has been added. Reconsideration is respectfully requested in view of the above amendments and the following remarks.

Applicants' Response to §103 Rejection over Leung

Claims 1-3, 7-11,13, 16, 18, 20-25, 29, 32 and 34 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No.6,596,298 to Leung et al. (hereinafter "Leung"). Applicants respectfully request reconsideration of this rejection based on the failure of Leung to suggest Applicants' claims, as amended herein.

The Examiner acknowledges that Leung does not teach a single example which includes every limitation of the elected species, but alleges that:

it would have been obvious to one of ordinary skill in the art to select the particular combination of the elected species from the broader disclosure of 6,596,298 because the reference teaches each of the ingredients of the elected invention is useful in the formation of edible water soluble films and there is no evidence of record to indicate particularly better or unexpected results obtained specifically when using the elected species. In particular, with respect to the combination of citric and malic acid and the proportions thereof in claim 8, the reference teaches both citric and malic acid are useful as the acidulate component. It would have been obvious to one of ordinary skill in the art to employ a mixture of the two because they are both taught to function equivalently in the film. The selection of a ratio of the two would have required only routine optimization of the intensity (citric acid) versus lasting effect (malic acid) of saliva stimulation within the level of ordinary skill in the art.

(Office Action at page 3).

The Examiner further alleges that:

The properties recited in claims 9 and 10 would be expected to be exhibited by the composition of the reference in that similar materials are combined using similar processes and the properties of a composition are indivisible from its identity. In that the reference teaches the film forming agent is taught as alginate or gum arabic, it would have been obvious to one of ordinary skill in the art to employ a mixture of the two because they are both taught to function equivalently in the film. Claims 13, 29, 32 and 34 include compositions having 0% sequestrant.

(Office Action at page 3).

Applicants have amended independent claim 1 herein to further define the claimed invention. In particular, amended claim 1 further defines the acidulent to include citric acid and malic acid in a ratio from 7:1 to 2:1, respectively. This amendment is supported by disclosure on page 4 of Applicants' specification and original claim 8. No new matter has been added.

The claimed combination of citric and malic acid in the specified ratio would not have been obvious to one skilled in the art. In particular, the Examiner asserted that "the selection of a ratio of citric acid to malic acid would have required only routine optimization of the intensity (citric acid) versus lasting effect (malic acid) of saliva stimulation within the level of ordinary skill in the art." (Office Action of 10/18/06, at page 3) Admittedly, a range of numbers can be found obvious where the range can be achieved through optimization. *See* MPEP §2144.05(II)(A). However, as noted in MPEP §2144.05(II)(B), a "particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation." As discussed, *inter alia*, on page 4 of Applicants' specification, the claimed ratio ensures an initial sour impact which transitions into a smooth prolonged sour taste. There is no disclosure or suggestion in Leung of a such a relative sour impact, nor is there any disclosure that the ratios of the specified organic acids can be used to achieve the relative sour impact. Without any appreciation of a relative sour impact or acid

ratios which achieve such an impact, there is no appreciation of this parameter as a result-effective variable. Moreover, as discussed above, there is no appreciation in Leung that citric acid and malic acid be combined, let alone that the two acidulents would be useful in the specified ratios. It is thus respectfully submitted that Lueng did not appreciate the claimed relative sour impact ranges as a result-effective variable. As such, determination of the claimed ranges for relative sour impact cannot be considered routine experimentation.

In addition, Applicants have amended independent claim 29 herein to further define the claimed invention. In particular, amended claim 29 further defines the acidulent to include a combination of organic acids present in an amount of about 20% by weight of the water-soluble film to about 37% by weight of the water-soluble film. This amendment is supported by disclosure on page 4 of Applicants' specification as filed. No new matter has been added.

As stated in detail above, nowhere in Leung is a combination of organic acids disclosed, taught or suggested. Applicants have amended claim 29 to recite the specific amount as between 20-37% by weight of the composition. Leung only discloses food acids present in an amount of "about 0.01 to about 12 wt %, preferably about 1 wt % to about 10 wt %, even more preferably about 2.5 wt % to about 6 wt %." (Leung, col 5, ll 51-53). Nowhere in Lueng is a combination of organic acids between 20-37% by weight of the composition disclosed, taught or suggested. As such, the reference fails to disclose each and every element of the claimed invention.

Withdrawal and reconsideration of the rejection is therefore respectfully requested. In view of the foregoing, claim 1 and thus claim 8 which depends therefrom, are now believed to be in proper form for allowance. A favorable reconsideration of the application on the merits is earnestly solicited.

In view of the above, it is respectfully submitted that there is no *prima facie* showing of obviousness based on the cited reference for independent claims 1 and 29 and all claims

depending therefrom. Applicants respectfully request reconsideration and withdrawal of the Section 103 rejection over Leung.

Applicants' Response to §103 Rejection over Leung in view of Virgalitto

Claim 19 is rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Leung in view of International Publication No. WO 03/04659 A1 to Virgalitto et al. (hereinafter "Virgalitto"). Applicants respectfully request reconsideration on the basis that the cited combination fails to suggest Applicants' claims, as amended herein.

The Examiner acknowledges that Leung does not identify waxes, but alleges that Virgalitto:

...teaches that waxes may be used as the emulsifier in edible water soluble film formulations. It would have been obvious to one of ordinary skill in the art to include a wax in the composition of the US reference because the WO reference teaches it would be expected to function as the emulsifier component.

(Office Action at page 3).

Applicants' claim 19 depends from claim 1, and thus, require all of the limitations of claim 1, as amended herein. As discussed in detail above with regard to amended claim 1, Lueng fails to disclose or suggest a relative sour impact which is obtained by the utilization of the recited ratio. Virgalitto was merely cited for its disclosure of emulsifiers and does not disclose teach or suggest using a combination of citric and malic acid in a ratio of from 7:1 to 2:1. Therefore, Virgalitto clearly fails to cure the deficiencies of Leung as a reference and their combination fails to arrive at the present invention. Withdrawal of this rejection is respectfully requested.

Applicants' Response to §103 Rejection over Virgalitto

Claims 1-3, 7-11, 13, 16, 18-25, 29, 32 and 35 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Virgalitto. Applicants respectfully request reconsideration of this rejection based on the failure of Virgalitto to suggest Applicants' claims, as amended herein.

The Examiner acknowledges that Virgalitto does not teach a single example which includes every limitation of the present invention, but alleges that:

it would have been obvious to one of ordinary skill in the art to select the particular combination of the elected species from the broader disclosure of 6,596,298 [sic] because the reference teaches each of the ingredients of the elected invention is useful in the formation of edible water soluble films and there is no evidence of record to indicate particularly better or unexpected results obtained specifically when using the elected species. In particular, with respect to the combination of citric and malic acid and the proportions thereof in claim 8, the reference teaches both citric and malic acid are useful as the acidulate component. It would have been obvious to one of ordinary skill in the art to employ a mixture of the two because they are both taught to function equivalently in the film. The selection of a ratio of the two would have required only routine optimization of the intensity (citric acid) versus lasting effect (malic acid) of saliva stimulation within the level of ordinary skill in the art.

The properties recited in claims 9 and 10 would be expected to be exhibited by the composition of the reference in that similar materials are combined using similar processes and the properties of a composition are indivisible from its identity. In that the reference teaches the film forming agent is taught as alginate or gum Arabic, it would have been obvious to one of ordinary skill in the art to employ a mixture of the two because they are both taught to function equivalently in the film. Claims 13, 29, 32 and 34 include compositions having 0% sequestrant.

(Office Action at page 4).

Applicants have amended independent claim 1 herein to further define the claimed invention. In particular, amended claim 1 further defines the acidulent to include citric acid and malic acid in a ratio from 7:1 to 2:1, respectively. This amendment is supported by disclosure on page 4 of Applicants' specification and original claim 8. No new matter has been added.

The claimed combination of citric and malic acid in the specified ration would not have been obvious to one skilled in the art. In particular, the Examiner asserted that the selection of a ratio of citric acid to malic acid “would have required only routine optimization of the intensity (citric acid) versus lasting effect (malic acid) of saliva stimulation within the level of ordinary skill in the art.” (Office Action of 10/18/2006, at page 3). Admittedly, a range of numbers can be found obvious where the range can be achieved through optimization. *See* MPEP §2144.05(II)(A). However, as noted in MPEP §2144.05(II)(B), a “particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation.” As discussed, *inter alia*, on page 4 of Applicants’ specification, the claimed ratio ensures an initial sour impact which transitions into a smooth prolonged sour taste. There is no disclosure or suggestion in Virgalitto of such a relative sour impact, nor is there any disclosure that the ratios of the specified organic acids can be used to achieve the relative sour impact. Virgalitto acknowledges that food acids may be incorporated to impart sourness. However, without any appreciation of a relative sour impact or acid ratios which achieve such an impact, there is no appreciation of this parameter as a result-effective variable. It is thus respectfully submitted that Virgalitto did not appreciate the claimed relative sour impact ranges as a result-effective variable. As such, determination of the claimed ranges for relative sour impact cannot be considered routine experimentation.

In view of the above, it is respectfully submitted that there is no *prima facie* showing of obviousness based on the cited reference for independent claim 1 and all claims which depend therefrom.

In addition, Applicants have amended independent claims 29 and 35 herein to further define the claimed invention. In particular, amended claims 29 and 35 further define the acidulent to include a combination of organic acids present in an amount of about 20% by weight

of the water-soluble film to about 37% by weight of the water-soluble film. This amendment is supported by disclosure on page 4 of Applicants' specification as filed. No new matter has been added.

As stated in detail above, nowhere in Virgalitto is a combination of organic acids disclosed, taught or suggested. Applicants have amended claims 29 and 35 to recite the specific amount as between 20-37% by weight of the composition. The food acids of the present invention are in their free form and not encapsulated. Although Virgalitto discloses food acids which may be included at levels greater than 8% based on the dry weight of the edible film formulation, it is explicitly stated that these food acids should be encapsulated since high levels "may adversely affect the properties of the film, for example the mechanical stability may be compromised and the hygroscopicity may increase." (Virgalitto, page 12). One skilled in the art would have no motivation to increase the level of food acid in its free form to the high level claimed in the present invention based on the teachings of Virgalitto. As such, Applicants respectfully request withdrawal of this rejection.

Applicants' Response to §103 Rejection over Leung or Virgalitto in view of Grillo

Claim 31 is rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Leung or Virgalitto in view of U.S. Patent No. 6,267,808 to Grillo et al. (hereinafter "Grillo"). Applicants respectfully request reconsideration on the basis that the cited combination fails to suggest Applicants' claims, as amended herein. ¹

In regards to claim 31, the Examiner acknowledges that the primary reference does not teach the addition of a salt of citric acid as the sequestrant, but alleges that:

¹ It is noted that the Examiner only specified claim 31 in the rejection heading on page 4 of the Office Action dated October 18, 2006. However, the Examiner additionally discusses claims 15, 35-37, 39-40 and 42 in the substance of the rejection. As such, it is assumed by the Applicants' that claims 15, 35-37, 39-40 and 42 were mistakenly omitted by the Examiner in the rejection header on page 4. If this is incorrect, please advise.

it would have been obvious to one of ordinary skill in the art to add sodium citrate to the compositions of the primary reference because Grillo teaches is [sic] works as a preservative.

(Office Action at pages 4-5).

Claim 31 depends upon independent claim 29. As stated in detail above, claim 29 has been amended to further define the acidulent to include a combination of organic acids present in an amount of about 20% by weight of the water-soluble film to about 37% by weight of the water-soluble film. Nowhere in Leung or Virgalitto is a combination of organic acids present in the amounts specified disclosed, taught or suggested. Grillo was merely cited for its disclosure of sodium citrate as a preservative and fails to disclose, teach or suggest a water-soluble film which includes a combination of organic acids present in an amount of about 20% to about 37% by weight of the water-soluble film.

In regards to claims 15 and 35, the Examiner acknowledges that the primary reference does not teach an alginate ester as the film former, but alleges that:

It would have been obvious to one of ordinary skill in the art to substitute PGA for the sodium alginate of the primary reference because the art recognizes them as equivalents.

(Office Action at page 5).

Claim 15 depends upon currently amended independent claim 35. As stated in detail above, claim 35 has been amended to further define the acidulent to include a combination of organic acids present in an amount of about 20% by weight of the water-soluble film to about 37% by weight of the water-soluble film. Nowhere in Leung or Virgalitto is a combination of organic acids present in the amounts specified disclosed, taught or suggested. Grillo was merely cited for its disclosure of polyethylene glycol alginate as a film former in edible films and fails to disclose, teach or suggest a water-soluble film which includes a combination of organic acids present in an amount of about 20% to about 37% by weight of the water-soluble film.

In regards to claims 36, 37, 39, 40 and 42, the Examiner acknowledges that the primary reference does not teach the addition of a salt of citric acid or the use of alginate ester, but alleges that:

It would have been obvious to one of ordinary skill in the art to add sodium citrate to the compositions of the primary reference because US 6267808 teaches it works as a preservative. It would have been obvious to one of ordinary skill in the art to substitute PGA for the sodium alginate of the primary reference because the art recognizes them as equivalents.

(Office Action at page 5).

Claim 36 depends upon currently amended independent claim 35. Claims 37, 39, 40 and 42 depend upon claim 36. As stated in detail above, claim 35 has been amended to further define the acidulent to include a combination of organic acids present in an amount of about 20% by weight of the water-soluble film to about 37% by weight of the water-soluble film. Nowhere in Leung or Virgalitto is a combination of organic acids present in the amounts specified disclosed, taught or suggested. Grillo was merely cited for its disclosure of sodium citrate as a preservative and polyethylene glycol alginate as a film former in edible films and fails to disclose, teach or suggest a water-soluble film which includes a combination of organic acids present in an amount of about 20% to about 37% by weight of the water-soluble film.

Applicants submit that the claims are patentable over the prior art and in proper form for allowance. Favorable action is respectfully requested.

No fees are believed to be due with this amendment. However, the Commissioner is hereby authorized to charge payment of any additional fees associated with this communication, or credit any overpayment, to Deposit Account No. 08-2461. Such authorization includes authorization to charge fees for extensions of time, if any, under 37 C.F.R. § 1.17 and also should be treated as a constructive petition for an extension of time in this reply or any future reply pursuant to 37 C.F.R. § 1.136.

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Amendment and Response dated January 18, 2007
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Docket No.: 1199-33
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Should the Examiner have any questions or comments concerning the above, the Examiner is respectfully invited to contact the undersigned attorney at the telephone number given below.

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